

WHAT IS CLAIMED IS:

Sub  
B1  
5

1. A procedure device capsule for transport of the intraluminal procedure device to a vascular, cardiac or other intraluminal situs which when inserted in the lumen of a blood vessel in the presence of blood flow comprises:

one layer comprising a tubular flexible substrate means having a generally cylindrical outside surface and a generally cylindrical inside surface characterized as capable of transporting the intraluminal procedure device to said situs.

2. An intraluminal procedure device for performance of intravascular or intracardiac or other intraluminal procedures at a situs which when inserted in the lumen of a host blood vessel in the presence of blood flow comprises:

a layer and a tube, wherein:

i) said layer, the barrier, comprising a durable flexible selectively permeable umbrella-like conical shaped substrate means with the conical end perforate and pointing downstream in the host blood vessel and the distal ends segmented into at least two segments to allow for differential expansion and contraction of the segments, characterized as capable of passage through said host blood vessel to a vascular or cardiac or other intraluminal situs and of differentially expanding said distal ends to attach to the walls of and stabilize at said situs, at a determined angle and for a determined length of time, allowing blood flow through said permeable substrate means preventing back pressure and embolization, and providing a working procedure region within the area confined by the inside of said barrier, and

ii) said tube, the working channel, comprising an elongated tubular durable flexible substrate means having a generally cylindrical outside surface and a

generally cylindrical inside surface which distal open end is attached at said situs of the perforation at the conical end of said barrier and which proximal end extends out the external entry to said host blood vessel, characterized as allowing external entry and utilization of instruments at said situs through passage of said instruments through said working channel, through the perforate conical end of said barrier and into the procedure working region.

3. A tissue cutter for removal of undesired tissue within the vascular or cardiac system or other anatomic lumens which when inserted into the intraluminal procedure device comprises:

at least one blade and a cable, wherein

i) said at least one blade comprising a collapsible blade, and characterized as capable of passage through a host blood vessel to a vascular or cardiac situs while collapsed within a working channel and then entry into the procedure working region, which when within the procedure working region comprises:

at least one collapsible sharp blade having at least one hinge mechanism allowing for collapsing and expansion and attached to zero or more other blades at varying angles to provide cutting surfaces at various angles, with said collapsible blade connected to

ii) said cable which when within the working channel comprises:

an elongated durable flexible wire which extends to the exterior of the host through the working channel, said cable characterized as capable of connection to an outside motor, and of controlling the speed of rotation of the blade(s).

4. The tissue cutter according to claim 3 wherein the proximal blade comprises a flexible wire capable of high speed rotation.

5. A valve introducer device for inserting a prosthetic valve device at a vascular, or cardiac situs which when inserted in the lumen of a blood vessel in the presence of blood flow comprises:

5 a layer, a tube, a pusher device and a bracer, wherein

10 i) said layer, the introducer capsule, comprising a tubular flexible substrate means having a generally cylindrical outside surface and a generally cylindrical inside surface and reinforced at the proximal end which is open, and having a semi-closed distal end with a perforate opening having a diameter approximately the same as the internal diameter of the tube, characterized as capable of transporting said prosthetic valve device to said situs,

15 ii) said tube, the introducer channel, comprising an elongated tubular durable flexible substrate means having a generally cylindrical outside surface and a generally cylindrical inside surface which proximal open end is attached at said situs of the distal opening of said introducer capsule and which distal end extends out the external entry of said blood vessel, and is characterized as containing a pusher channel of a pusher device within its lumen,

20 iii) said pusher device comprising a disc and a tube, said disc of said pusher device comprising a generally circular disc, with a generally flat distal surface, a generally flat proximal surface and a central opening, and made of a durable, flexible material, having its proximal surface abut said prosthetic valve device contained within said introducer capsule, and attached at said central opening of its distal surface is said proximal end of said tube, which comprises:

25 an elongated flexible cylinder made of durable, flexible, non-thrombogenic material, having a generally cylindrical outside surface and a generally cylindrical inside surface and a smaller internal diameter than that used in said introducer channel, and is

characterized as capable of maintaining its structural integrity such that it does not distort upon the application of external pressure, of being contained within the lumen of said introducer channel with its distal end extending beyond the vascular entry point via said introducer channel, of allowing passage of a mounting balloon and guide wire, and of advancing within the lumen of said introducer channel, upon application of external pressure to advance said pusher disc, and thereby said prosthetic valve device within said introducer capsule, and

iv) said bracer, comprising a differentially expandable device circumferentially attached to the external surface of said introducer capsule at said capsule's proximal end and is characterized as having the capability of expanding to hold said introducer capsule in a precise position during delivery of said prosthetic valve device.

6. A prosthetic valve device for supplanting or replacing a cardiac valve which when inserted in the lumen of a blood vessel, in extra-anatomic conduits or at a cardiac valve annulus situs in the presence of blood flow comprises:

a sleeve, a valve and an annulus, wherein

i) said sleeve comprises a tubular flexible substrate means having a generally cylindrical outside layer secured to

(ii) said compressible annulus at its base comprising a mounting ring by a series of mounting pins, and a generally cylindrical inside surface contacting an inner layer comprising

(iii) said valve, characterized as capable of insertion into a cardiac or vascular situs through a host blood vessel, host compatible and capable of autonomous operation, which when inserted in said situs in the presence of blood flow comprises a flexible annulus having a generally cylindrical outside surface

and a generally cylindrical inside surface containing at least one cusp to permit blood flow through said cusp in a single direction;

iv) attachment means comprising at said first and second open ends of said cusp to permit fixation of said device at least at or above said annulus of said dysfunctional valve by the mounting ring which comprises;

v) a flexible annulus having a generally cylindrical inside surface and a generally cylindrical outside surface containing a series of mounting pins to fixate said prosthetic valve device at said situs.

7. A valve, characterized as capable of insertion into a cardiac or vascular situs through a host blood vessel, host compatible and capable of autonomous operation, which when inserted in said situs in the presence of blood flow comprises:

a flexible annulus having a generally cylindrical outside surface and a generally cylindrical inside surface containing at least one cusp to permit blood flow through said cusp in a single direction.

8. A valve according to claim 7 further comprising attachment means comprising at said first and second open ends of said cusp to permit fixation of said device at least at or above said annulus of said dysfunctional valve by the mounting ring.

9. A mounting ring to fixate an attached device at a situs characterized as capable of insertion into a cardiac or vascular situs through a host blood vessel, host compatible and capable of autonomous operation, which when inserted in said situs in the presence of blood flow comprises:

a flexible annulus having a generally cylindrical outside surface and a generally cylindrical

inside surface containing a series of mounting pins to fixate said attached device at the said situs.

5 10. A valve replacement system for supplanting or replacing a cardiac valve which when inserted in the lumen of a blood vessel, in extra-anatomic conduits or at a cardiac valve annulus situs in the presence of blood flow comprises:

10 a procedure device capsule, an intraluminal procedure device, a tissue cutter, a valve introducer device, and a prosthetic valve device.

15 11. A method for replacing a cardiac or other valve or prosthesis endovascularly which method comprises:

20 a procedure device capsule contains and transports a intraluminal procedure device endovascularly, through surface insertion of and passage through the host's vasculature, to a valve situs whereby a barrier of said intraluminal procedure device exits from said procedure device capsule, expands in a controlled and adjustable manner, abuts the lumen of the vessel, and encircles the valve situs, and upon which:

25 a tissue cutter travels through a working channel of said intraluminal procedure device to said valve situs and upon arrival at said situs cuts and removes the old valve, prosthesis or other designated tissue, and any resulting loose matter is trapped by said barrier or is removed from the host's vasculature through suction and other tissue retrieval device  
30 inserted via said working channel, and upon removal of said old valve, prosthesis or other tissue:

35 said barrier is contracted, said intraluminal procedure device is withdrawn and secured into said procedure device capsule which is then removed, and a valve introducer device containing a prosthetic valve device transports said prosthetic valve to said valve

situs via endovascular means, and upon reaching said valve situs:

5        said valve introducer device's bracer expands to position said valve introducer device correctly for insertion of said prosthetic valve device at said valve situs, a pusher device of said valve introducer device advances to expel said prosthetic valve device from said introducer capsule, upon which a balloon which has been introduced by a guide wire via a pusher channel of said  
10        pusher device, is inflated at the situs to securely mount said prosthetic valve device, and upon secure fixation of said prosthetic valve device at said situs:

15        said bracer is contracted, said balloon deflated, and said valve introducer device, said balloon and said guide wire are removed from said host's vasculature.

20        12. A method of supplanting a cardiac or other valve or prosthesis endovascularly which method comprises:

25        a valve introducer device containing a prosthetic valve device transports it to a valve fixation situs endovascularly, through surface insertion of and passage through the host's vasculature, to the fixation situs and upon reaching the fixation situs:

30        a valve introducer device's bracer expands to position said valve introducer device correctly for insertion of said prosthetic valve device at said valve situs, a pusher device of said valve introducer device advances to expel a prosthetic valve device from an introducer capsule, upon which a balloon which has been introduced by a guide wire via a pusher channel of said  
35        pusher device, is inflated at said situs to securely mount said prosthetic valve device, and upon secure fixation of said prosthetic valve device at said situs:

      said bracer is contracted, said balloon deflated, and said valve introducer device, said balloon

and said guide wire are removed from said host's vasculature.

5 13. A method of use extracting host valves or tissue endovascularly which method comprises:  
a procedure device capsule contains and transports an intraluminal procedure device endovascularly, through surface insertion of and passage through a host's vasculature, to a situs for removal whereby a barrier of said intraluminal procedure device exits from  
10 said procedure device capsule, expands in a controlled and adjustable manner, abuts the lumen of said host vessel, and encircles said removal situs, and upon which:

15 a tissue cutter travels through a working channel in said procedure device to said removal situs and upon arrival at said situs cuts and removes the old valve, prosthesis or other designated tissue, and any resulting loose matter is trapped by said barrier or is removed from said host's vasculature through suction and  
20 other tissue retrieval device inserted via said working channel, and upon removal of said old valve, prosthesis or other tissue, said barrier is contracted, said intraluminal procedure device is withdrawn into and  
25 secured in said procedure device capsule, which is then removed.

14. A method of emboli free endovascular procedures which method comprises:

30 a procedure device capsule contains and transports an intraluminal procedure device endovascularly, through surface insertion of and passage through a host's vasculature, to a situs for procedure whereby a barrier of said intraluminal procedure device exits  
35 from said procedure device capsule, expands in a controlled and adjustable manner, abuts the lumen of said vessel, and encircles said procedure situs, and upon which:



